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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

HM12/0313

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ART UNIT

PAPER NUMBER

1635

DATE MAILED:

03/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
09/428,371Applicant(s)
Soderlund et alExaminer
Zara, JaneGroup Art Unit
1635☐ Responsive to communication(s) filed on _____☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 41-52 and 78-83 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.☒ Claim(s) 41-52 and 78-83 is/are rejected.☐ Claim(s) _____ is/are objected to.☐ Claims _____ are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☒ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.☐ received in Application No. (Series Code/Serial Number) _____☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☐ Notice of References Cited, PTO-892☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Application/Control Number: 09/428,371

Page 2

Art Unit: 1635

DETAILED ACTION

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). The updated status of Application Serial No. 08/772,512, now US Patent No. 6,022,705, has to be included in the specification.

Specification

The SEQ ID Nos are used incorrectly in various parts of the specification. On page 23, SEQ ID NO: 3 is referred to as a nucleotide sequence rather than as an amino acid sequence (i.e. lines 21-24). These inconsistencies must be corrected by the Applicants.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-52 and 78-83 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

Art Unit: 1635

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to methods of screening a chemical agent for its ability to modify sodium channel function comprising expression of a voltage-sensitive sodium channel (VSSC) in a host cell, or additionally coexpressing tip E protein in a host cell, exposing the cell to a chemical agent and determining whether the chemical agent modifies the function of the VSSC by monitoring either sodium or guanidinium transport through said VSSC, wherein said VSSC has been determined to confer either susceptibility or resistance to an insecticide in *Musca domestica*.

The specification as filed fails to provide any particular guidance for the translation, characterization of translated protein(s), transfection or functional expression of gene products of SEQ ID Nos: 1 and 2 in suitable host cells. The specification as filed teaches only the isolation and determination of nucleic acid sequences of SEQ ID Nos: 1 and 2 and the determination of putative amino acid sequences which are encoded by these genes. One skilled in the art would not accept on its face the purported amino acid sequence determinations derived from nucleic acid sequences as being representative or correlative of translated functional protein products in vitro or in a host cell and further with methods of assaying chemical agents which modify protein function in view of the lack of guidance in the specification and known unpredictability associated with the functional expression of a gene of known sequence and the determination of assay parameters for normal and altered functions of an expressed protein or proteins in a host


Art Unit: 1635

cell. The specification as filed fails to provide any particular guidance which resolves the known unpredictability in the art associated with the functional expression of a nucleotide sequence and the determination of parameters to be used in assaying for altered function of a purported protein and specifically regarding the instant nucleotide sequences (SEQ ID NOS: 1 and 2) encoding purported VSSC's conferring either susceptibility or resistance to an insecticide in *Musca domestica*.

The quantity of experimentation required to practice the invention as claimed would require the de novo expression of the purported VSSC's which are encoded by SEQ ID Nos: 1 and 2 in *Xenopus* oocytes, *Drosophila Schneider* cells, *Drosophila Kc* cells, *SF9* cells and *High Five* cells. The de novo determination of parameters which define normal function of said purported VSSC's in a host cell, as well as examples of positive and negative controls for chemical agents which modify VSSC function in said host cell are also required to practice the invention as claimed. Since the specification fails to provide any particular guidance in this regard, and since determination of these factors for a particular nucleic acid sequence is highly unpredictable, it would require undue experimentation to practice the invention claimed.

Art Unit: 1635

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (703)-306-5820. The examiner's supervisory primary examiner is George Elliott who can be contacted at (703)-308-4003.



George C. Elliott, Ph.D.
Supervisory Patent Examiner
Technology Center 1600

JZ

March 7, 2000